



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/647,739	08/25/2003	Manuel Guzman Pastor	A34700 PCT USA-I	2301
21003 7590 05/16/2007 BAKER BOTTS L.L.P. 30 ROCKEFELLER PLAZA 44TH FLOOR NEW YORK, NY 10112-4498			EXAMINER ANDERSON, JAMES D	
			ART UNIT 1614	PAPER NUMBER
			MAIL DATE 05/16/2007	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

**Office Action Summary**

Application No.

10/647,739

Applicant(s)

GUZMAN PASTOR ET AL.

Examiner

James D. Anderson

Art Unit

1614

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 20 February 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 16 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 16 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

**CLAIM 16 IS PRESENTED FOR EXAMINATION**

Applicants' amendment filed 2/20/2007 has been received and entered into the application. In light of the amendments, as well as the remarks of applicants at pages 3-4 of their amendment, the rejections of the claims under 35 U.S.C. § 102(b) and 35 U.S.C. § 112, 2<sup>nd</sup> paragraph, as set forth in the previous Office action dated 11/21/2006 are hereby withdrawn.

Upon further consideration, the following rejection is newly applied. In light of the new rejection being applied against the pending claim, this Office Action is **Non-Final**.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. § 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR § 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. § 103(c) and potential 35 U.S.C. § 102(e), (f) or (g) prior art under 35 U.S.C. § 103(a).

Art Unit: 1614

Claim 16 is rejected under 35 U.S.C. § 103(a) as being unpatentable over Sanchez *et al.* (FEBS Letters, 1998, vol. 436, pages 6-10) in view of Uesugi *et al.* (Acta Neuropathol., 1998, vol. 96, pages 351-356).

The instant claim recites a method of treating glioblastomas comprising administering  $\Delta^9$ -tetrahydrocannabinol ( $\Delta^9$ -THC) or  $\Delta^8$ -tetrahydrocannabinol ( $\Delta^8$ -THC).

Sanchez *et al.* disclose that  $\Delta^9$ -THC induces apoptosis in C6 glioma cells (Abstract; Figures). The authors suggest that the challenge of C6.9 cells to cannabinoids may be a useful model to study the molecular mechanisms involved in apoptosis in cells of glial origin (page 9, right column).

C6 glioma cells are art-recognized as a model of glioblastomas. For example, Uesugi *et al.* disclose the use of a rat glioma cell line (C6) as a rat glioma model (Abstract; page 351). Apoptosis of glioma cells is induced by the administration of several agents, including anti-tumor drugs (*id.*). C6 glioma cells are traditionally used as a model of glioblastoma multiforme when implanted in rat brains (page 354).

The instantly claimed method of treating glioblastomas by administering  $\Delta^9$ -THC or  $\Delta^8$ -THC would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made. Sanchez *et al.* demonstrate that  $\Delta^9$ -THC induces apoptosis in C6 glioma cells. As such, the skilled artisan would have been motivated to use  $\Delta^9$ -THC to treat glioblastomas given the fact that C6 gliomas cells were recognized in the art as a model of glioblastoma growth, invasion and metastases. Further, the skilled artisan would have been imbued with at least a reasonable expectation that a compound that induces apoptosis of C6 glioma cells *in vitro* would also be effective in treating a glioblastoma *in vivo*.

Art Unit: 1614

Accordingly, the claim is deemed properly rejected under 35 U.S.C. § 103 as being *prima facie* obvious over the cited references.


***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James D. Anderson whose telephone number is 571-272-9038.


The examiner can normally be reached on MON-FRI 9:00 am - 5:00 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

  
James D. Anderson, Ph.D.  
Patent Examiner  
AU 1614

May 10, 2007

  
PHYLLIS SPIVACK  
PRIMARY EXAMINER  
5/10/07